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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,206	06/26/2001	Thomas J. Brennan	R-171	9330

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EXAMINER	
BERTOGLIO, VALERIE E	

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/892,206	Applicant(s) BRENNAN ET AL.	
	Examiner Valerie E. Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a nucleic acid construct and methods of making the construct, classified in class 536, subclass 23.1.

II. Claims 5-7, 9, 27, drawn to cells with a disruption in an anaphylatoxin C3a receptor gene, classified in class 435, subclass 325.

III. Claims 8, 17-25, drawn to a transgenic animal comprising a disruption in an anaphylatoxin C3a gene, classified in class 800, subclass 13.

IV. Claims 11, 12, 28-30, drawn to methods of using a transgenic animal comprising a disruption in an anaphylatoxin C3a gene to test agents, classified in class 800, subclass 3.

V. Claims 10 and 26, drawn to a method of making a transgenic animal, classified in class 800, subclass 21.

VI. Claims 13-15, 31, 32, drawn to methods of using cells with a disruption in an anaphylatoxin C3a gene to test agents wherein the cell is from a transgenic animal, classified in class 435, subclass 325.

VII. Claims 16 and 33, drawn to an agent , classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the nucleic acid construct can be used as a probe while the cells can be used in in vitro assays to determine agents that modulate anaphylatoxin C3a expression. Furthermore, the protocols and reagents required for the nucleic

acid and the cells are materially distinct and separate. The burden required to search the nucleic acid construct and the cells together, each having materially different structures, would be undue.

Inventions I and III are patentably distinct because, the nucleic acid construct can be used as a probe while the transgenics can be used in in vivo assays to determine agents that modulate anaphylatoxin C3a expression. The burden required to search the nucleic acid construct and the transgenic together, each having materially different structures, would be undue.

Inventions I and IV are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vivo* assays to determine agents that modulate anaphylatoxin C3a expression. The protocols and reagents required for the nucleic acid and using the transgenics are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the methods together, each having materially different structures, would be undue.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid construct can be used as a DNA probe.

Inventions I and VI are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vitro* assays to determine agents that modulate anaphylatoxin C3a expression. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the

methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the method together, each having materially different structures, would be undue.

Inventions I and VII are patentably distinct because, the nucleic acid construct can be used as a probe while the agent can be used to modulate anaphylatoxin C3a expression. The protocols and reagents required for the nucleic acid and the agent are materially distinct and separate. The construct does not require the agent and the agent does not require the construct. Furthermore, the burden required to search the nucleic acid construct and the agent together, each having materially different structures, would be undue.

Inventions II and III are patentably distinct because, the cells can be used in in vitro assays to determine differential gene expression while the transgenics can be used in in vivo assays to determine agents that modulate anaphylatoxin C3a expression. Furthermore, the protocols and reagents required for the cells and the transgenics are materially distinct and separate. The burden required to search the cells and the transgenic together, each having materially different structures, would be undue.

Inventions II and IV are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used in *in vivo* assays to determine agents that modulate anaphylatoxin C3a expression. The protocols and reagents required for the cells and methods of using the transgenic are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the method of using a transgenic together, each having materially different structures, would be undue.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can be used for in vitro assays to determine agents that modulate anaphylatoxin C3a expression.

Inventions II and VI are related as product and process of use. In the instant case the method of testing agents can be done *in vivo* using transgenics comprising a disruption in anaphylatoxin C3a while the cells can be used in *in vitro* assays to determine differential gene expression between cells with a disruption in anaphylatoxin C3a and wild type cells.

Inventions II and VII are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the agent can be used to modulate anaphylatoxin C3a expression. The cells do not require the agent and the agent does not require the construct. Furthermore, the burden required to search the cells and the agent, each having materially different structures, would be undue.

Inventions III and IV are related as product and process of use. In the instant case the method of testing agents can be done *in vitro* using cells comprising a disruption in anaphylatoxin C3a. Furthermore, the transgenic can be used to determine the role of anaphylatoxin in vivo.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic can be made by injecting the blastocyst with DNA.

Inventions III and VI are patentably distinct because the transgenics can be used to determine the role of anaphylatoxin C3a in vivo while methods of using the cells are process steps with the purpose of identifying agents. Furthermore, the protocols and reagents required for the transgenics and the methods are materially distinct and separate. The burden required to search the transgenic and the methods of using cells together, each having materially different structures, would be undue.

Inventions III and VII are patentably distinct because the transgenics can be used to determine the role of anaphylatoxin C3a in vivo while the agent is used to modulate anaphylatoxin C3a. The protocols and reagents required for the transgenics and the agent distinct and separate. The burden required to search the transgenic and the agent together, each having materially different structures, would be undue.

The methods of each of inventions IV-VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The purpose of Inventions IV-VI are different. The transgenic used in Invention IV is not required for the methods of Inventions V or VI. The burden required to seach Inventions IV-VI together would be undue.

Inventions IV and VII are patentably distinct because, the agent can be identified from in vitro assays using cells harboring a disruption in anaphylatoxin C3a. The agent does not require the methods of using the transgenic and the methods do not require the agent. Furthermore, the

burden required to search the transgenic and the agent, each having materially different structures, would be undue.

Inventions V and VII are patentably distinct because, the method can be used to generate a transgenic animal while the agent can be used to modulate anaphylatoxin C3a expression. The protocols and reagents required for the transgenic and the agent are materially distinct and separate. The transgenic does not require the agent and the agent does not require the construct. Furthermore, the burden required to search the transgenic and the agent, each having materially different structures, would be undue.

Inventions VI and VII are patentably distinct because, the agent can be identified from in vivo assays using a transgenic animal harboring a disruption in anaphylatoxin C3a. The agent does not require the methods of using the cells and the methods do not require the agent. Furthermore, the burden required to search the cells and the agent, each having materially different structures, would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER